# ASPIRIN- aspirin tablet REMEDYREPACK INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### Rugby 44-157

## Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)\*
\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves:
  - headache
  - pain and fever of colds
  - toothache
  - menstrual pain
  - muscle pain
  - minor pain of arthritis

## Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- shock
- facial swelling
- hives
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

#### Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

#### Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

### Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

## If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months or pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

## Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets

every 6 hours not to exceed 12 tablets in 24 hours unless directed by a doctor

• children under 12 years: do not use unless directed by a doctor

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

### Inactive ingredients

corn starch, hypromellose, polyethylene glycol, propylene glycol

#### Questions or comments?

1-800-645-2158

DRUG: Aspirin

**GENERIC: Aspirin** 

DOSAGE: TABLET

ADMINSTRATION: ORAL

NDC: 70518-3069-0

COLOR: white

SHAPE: ROUND

SCORE: No score

SIZE: 10 mm

IMPRINT: 44;157;ASPIRIN

PACKAGING: 30 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

• ASPIRIN 325mg in 1

#### **INACTIVE INGREDIENT(S):**

- STARCH, CORN
- HYPROMELLOSE, UNSPECIFIED
- PROPYLENE GLYCOL
- POLYETHYLENE GLYCOL, UNSPECIFIED

## **Aspirin**

Pain Reliever/Fever Reducer

325 mg

Tablet QTY: 30

NDC #: 70518-3069-00

Expires: LOT #:

Source NDC: 00536-1054-29

MFG: Rugby Labs, Livonia, MI 48150

Keep this and all medication out of the reach of children



remedy repack Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP] Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

NOT FOR RETAIL SALE

#### **ASPIRIN**

aspirin tablet

#### **Product Information**

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:70518-3069(NDC:0536-1054)

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

## **Inactive Ingredients**

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

#### **Product Characteristics**

- 104464 0144 4040 1040			
Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;157;ASPIRIN
Contains			

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# Item Code Package Description Marketing Start Marketing End
Date Date

1 NDC:70518- 3069-0	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/10/2021		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph no final	part343	04/10/2021		

## Labeler - REMEDYREPACK INC. (829572556)

Revised: 4/2021 REMEDYREPACK INC.